MAR 13 1996

K955863

510 (k) SUMMARY

I. ADMINISTRATIVE

Submitter: Mölnlycke/Scott Health Care
500 Baldwin Tower
Eddystone, PA 19022

Contact Person: Mike Drummond
(610) 499-3375

Date of Preparation: December 26, 1995

II. DEVICE NAME

Proprietary Name: AllDress®
Common Name: Sterile Multi-Layered Wound Dressing
Classification Name: Wound Dressing
Regulatory Class: Unclassified
Product Code: 79FRO

III. PREDICATE DEVICE

AllDress® Multi Layered Wound Dressing (Scott Health Care; K945206)

IV. DEVICE DESCRIPTION

The AllDress® Multi Layered Wound Dressing is a sterile wound dressing composed of an absorbent layer with a non-adherent wound contact surface. The absorbent layer is bonded to an adhesive backing layer which secures the dressing to the skin around the wound. Dressings are supplied in sizes of 2¼"x 2¼" (1"x 1" wound contact surface); 6"x 6" (4"x 4" wound contact surface); 4"x 4" (2"x 2" wound contact surface); and 6"x 8" (4"x 6" wound contact surface). The wound contact side of the dressing is covered with scored siliconized release paper to permit aseptic application.

The AllDress® Multi Layered Wound Dressing represents a modified version of the currently marketed AllDress® Multi Layered Wound Dressing (K945206) and is identical to the predicate device with respect to function and intended use. to the Comfeel® Plus Ulcer Dressing (K941263). The composition of the backing layer of the modified product has been changed to improve the wound barrier properties of the dressing.

Biocompatibility of the modified device has been established by intracutaneous toxicity test (rabbit), systemic toxicity test (mice), muscle implantation test (rabbit), primary skin irritation test (rabbit), hemolysis test (*In Vitro*), cytotoxicity test (*In Vitro*), and delayed hypersensitivity test (guinea pig). In addition, bacterial penetration (strike-through) studies with *S. aureus* and *P. aeruginosa* and ASTM

IV. DEVICE DESCRIPTION (continued)

viral penetration test with ϕX174 bacteriophage were conducted to demonstrate the effective performance of the dressing as a bacterial and viral barrier.

V. INTENDED USE

For the dressing and management of chronic/open wounds.

VI. CONCLUSION

The technological characteristics of the modified AllDress® Multi Layered Wound Dressing are the same as to those of the predicate device, except for compositional changes intended to improve its wound barrier properties of the product. Biocompatibility and performance testing of the modified device have demonstrated safety as well as effective wound barrier performance. Accordingly, Mölnlycke/Scott Health Care has concluded that the modified device is safe and effective for its intended use and performs at least as well as the legally marketed predicate device.